

AMENDMENTS TO THE CLAIMS

1. (Currently amended) A method for evaluating the a quality of a calibration of an analyte sensor, the method comprising:

receiving a data stream from an analyte sensor, including one or more sensor data points;

receiving reference data from a reference analyte monitor, including ~~two~~ one or more reference data points;

providing at least ~~two~~ one matched data pairs pair by matching reference analyte data to substantially time corresponding sensor data;

forming a calibration set including said at least ~~two-matching-data-pairs~~ one matched data pair;

evaluating a quality of said calibration set using a data association function;

~~creating a conversion function based on said calibration set;~~

~~receiving additional sensor data from the analyte sensor, wherein the step of receiving additional sensor data from the analyte sensor is performed after the step of creating a conversion function;~~

converting sensor data into calibrated data using said ~~conversion function~~ calibration set; and

~~evaluating the quality of said calibration set using a data association function~~
providing the calibrated data to a user interface only when the data association is above a predetermined threshold.

2. (Original) The method of claim 1, wherein the step of receiving sensor data comprises receiving a data stream that has been algorithmically smoothed.

3. (Original) The method of claim 1, wherein the step of receiving sensor data comprises algorithmically smoothing said data stream.

4. (Original) The method of claim 1, wherein the step of receiving sensor data comprises receiving sensor data from a substantially continuous glucose sensor.

5. (Original) The method of claim 1, wherein the step of receiving sensor data comprises receiving sensor data from an implantable glucose sensor.

6. (Original) The method of claim 1, wherein the step of receiving sensor data comprises receiving sensor data from a subcutaneously implantable glucose sensor.

7. (Original) The method of claim 1, wherein the step of receiving reference data comprises receiving reference data from a self-monitoring blood glucose test.

8. (Original) The method of claim 1, wherein the step of receiving reference data comprises downloading reference data via a cabled connection.

9. (Original) The method of claim 1, wherein the step of receiving reference data comprises downloading reference data via a wireless connection.

10. (Original) The method of claim 1, wherein the step of receiving reference data from a reference analyte monitor comprises receiving within a receiver internal communication from a reference analyte monitor integral with said receiver.

11. (Canceled)

12. (Currently amended) The method of claim 1, wherein the step of evaluating ~~the~~ a quality of said calibration set based on a data association function comprises performing linear least squares regression.

13. (Canceled)

14. (Currently amended) The method of claim ~~13~~ 1, wherein the step of evaluating ~~the~~ a quality of said calibration set based on data association comprises performing linear least squares regression and wherein the ~~step of setting a predetermined~~ threshold ~~hold includes~~ is an R-value threshold of 0.79.

15-16. (Canceled)

17. (Currently amended) The method of claim ~~15~~ 1, wherein the step of providing ~~an output~~ calibrated data includes alerting the user dependent upon ~~the~~ a quality of said calibration.

18. (Currently amended) The method of claim ~~15~~ 1, wherein the step of providing ~~an output~~ calibrated data includes altering the user interface dependent upon ~~the~~ a quality of said calibration.

19. (Currently amended) The method of claim ~~15~~ 1, wherein the step of providing ~~an output~~ calibrated data includes at least one of providing color-coded information, trend information, directional information, and fail-safe information.

Appl. No. : 10/633,329
Filed : August 1, 2003

20. (Currently amended) A system for evaluating the a quality of a calibration of an analyte sensor, the system comprising:

means for receiving a data stream from an analyte sensor, a plurality of time-spaced sensor data points;

means for receiving reference data from a reference analyte monitor, including two one or more reference data points;

means for providing two one or more matched data pairs by matching reference analyte data to substantially time corresponding sensor data;

means for forming a calibration set including at least two one matched data pairs pair;

~~means for creating a conversion function based on said calibration set;~~

means for ~~prospectively~~ converting sensor data into calibrated data using said ~~conversion function~~ calibration set; and

~~means for evaluating the quality of said calibration set based on a data-association function~~ means for providing calibrated data only when the data association is above a predetermined threshold.

21. (Original) The system of claim 20, wherein said means for receiving sensor data comprises means for receiving sensor data that has been algorithmically smoothed.

22. (Original) The system of claim 20, wherein said means for receiving sensor data comprises means for algorithmically smoothing said receiving sensor data.

23. (Original) The system of claim 20, wherein said means for receiving sensor data comprises means for receiving sensor data from substantially continuous glucose sensor.

24. (Original) The system of claim 20, wherein said means for receiving sensor data comprises means for receiving sensor data from an implantable glucose sensor.

25. (Original) The system of claim 20, wherein said means for receiving sensor data comprises means for receiving sensor data from subcutaneously implantable glucose sensor.

26. (Original) The system of claim 20, wherein said means for receiving reference data comprises means for receiving reference data from a self-monitoring blood glucose test.

27. (Original) The system of claim 20, wherein said means for receiving reference data comprises means for downloading reference data via a cabled connection.

28. (Original) The system of claim 20, wherein said means for receiving reference data comprises means for downloading reference data via a wireless connection.

29. (Original) The system of claim 20, wherein said means for receiving reference data from a reference analyte monitor comprises means for receiving within a receiver internal communication from a reference analyte monitor integral with said receiver.

30. (Original) The system of claim 20, wherein said means for evaluating the quality of said calibration set comprises means for performing one of linear regression, non-linear regression, rank correlation, least mean square fit, mean absolute deviation, and mean absolute relative difference.

31. (Original) The system of claim 20, wherein said means for evaluating the quality of said calibration set comprises means for performing linear least squares regression.

32. (Canceled)

33. (Currently amended) The system of claim ~~32~~ 20, ~~wherein said~~ further comprising means for evaluating ~~the a~~ quality of said calibration set ~~comprises based on a data association function comprising means for performing~~ linear least squares regression and wherein said means ~~for setting a predetermined threshold hold includes is~~ an R-value threshold of 0.71.

34-35. (Canceled)

36. (Currently amended) The system of claim ~~34~~ 20, wherein said means for providing ~~an output~~ calibrated data includes means for alerting the user dependent upon ~~the a~~ quality of said calibration.

37. (Currently amended) The system of claim ~~34~~ 20, wherein said means for providing ~~an output~~ calibrated data includes means for altering the user interface dependent upon ~~the a~~ quality of said calibration.

38. (Currently amended) The system of claim ~~34~~ 20, wherein said means for providing ~~an output~~ calibrated data includes at least one of providing color-coded information, trend information, directional information, and fail-safe information.

39. (Currently amended) A computer system for evaluating ~~the~~ a quality of a calibration of an analyte sensor, the computer system comprising:

a sensor data receiving module that receives a data stream comprising a plurality of time spaced sensor data points from a substantially continuous analyte sensor;

a reference data receiving module that receives reference data from a reference analyte monitor, including ~~two~~ one or more reference data points;

a data matching module that forms ~~two~~ one or more matched data pairs by matching reference data to substantially time corresponding sensor data;

a calibration set module that forms a calibration set including at least ~~two~~ one matched data ~~pairs~~ pair;

~~a conversion function module that creates a conversion function using said calibration set;~~

a sensor data transformation module that ~~prospectively~~ converts sensor data into calibrated data using said ~~conversion function~~ calibration set; and

an interface control module that displays said calibrated data only when the data association is above a predetermined threshold

~~a quality evaluation module that evaluates the quality of said calibration set based on a data association function.~~

40. (Original) The computer system of claim 39, wherein said sensor data receiving module receives sensor data that has been algorithmically smoothed.

41. (Original) The computer system of claim 39, further comprising a data smoothing module that algorithmically smoothes sensor data received from said sensor data receiving module.

42. (Original) The computer system of claim 39, wherein said sensor data receiving module is adapted to receive sensor data from substantially continuous glucose sensor.

43. (Original) The computer system of claim 39, wherein said sensor data receiving module is adapted to receive sensor data from an implantable glucose sensor.

44. (Original) The computer system of claim 39, wherein said sensor data receiving module is adapted to receive sensor data from subcutaneously implantable glucose sensor.

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45. (Original) The computer system of claim 39, wherein said reference data receiving module is adapted to receive reference data from a self-monitoring blood glucose test.

46. (Original) The computer system of claim 39, wherein said reference data receiving module is adapted to download reference data via a cabled connection.

47. (Original) The computer system of claim 39, wherein said reference data receiving module is adapted to download reference data via a wireless connection.

48. (Original) The computer system of claim 39, wherein said reference data receiving module is adapted to receive reference data from a reference analyte monitor integral with said receiver.

49. (Canceled)

50. (Original) The computer system of claim 39, ~~wherein said~~ further comprising a quality evaluation module performs that evaluates a quality of said calibration set based on a data association function comprising a linear least squares regression.

51. (Canceled)

52. (Currently amended) The computer system of claim ~~51~~ 39, ~~wherein said further comprising a quality evaluation module performs that evaluates a quality of said calibration set based on a data association function comprising a linear least squares regression and wherein the predetermined threshold of said data association function includes~~ is an R-value threshold of at least 0.79.

53-54. (Canceled)

55. (Currently amended) The computer system of claim ~~53~~ 39, wherein said interface control module alerts the user based upon ~~the~~ a quality of said calibration set.

56. (Currently amended) The computer system of claim ~~53~~ 39, wherein said interface control module alters the user interface based upon ~~the~~ a quality of said calibration set.

57. (Currently amended) The computer system of claim ~~53~~ 39, wherein said interface control module provides at least one of color-coded information, trend information, directional information, and fail-safe information.

58. (Currently amended) A method for evaluating the a quality of a calibration of an analyte sensor, the method comprising:

receiving a data stream from an analyte sensor, including one or more sensor data points;

receiving reference data from a reference analyte monitor, including ~~two~~ one or more reference data points;

providing at least ~~two~~ one matched data pairs pair by matching reference analyte data to substantially time corresponding sensor data;

forming a calibration set ~~including said at least~~ comprising no more than two matching data pairs for a single day;

~~creating a conversion function based on said calibration set;~~

~~prospectively converting additional sensor data into calibrated data using said conversion function; and~~

evaluating the a quality of said calibration set based on a data an association function ~~selected from the group consisting of linear regression, non-linear regression, rank correlation, least mean square fit, mean absolute deviation, and mean absolute relative difference~~ of reference analyte data and substantially time corresponding sensor data for at least one matched data pair.

59. (Currently amended) A method for evaluating ~~the~~ a quality of a calibration of an analyte sensor, the method comprising:

receiving analyte sensor data from an analyte sensor;

receiving reference data from a reference analyte monitor;

providing at least ~~two~~ one matched data pairs pair by matching reference analyte data to substantially time corresponding sensor data;

~~creating a conversion function based on said at least two matched data pairs;~~

~~converting sensor data into substantially real-time analyte values using said conversion function as sensor data is continuously or intermittently received from the sensor~~ evaluating a quality of said at least one matched data pair based on an association of reference analyte data and substantially time corresponding sensor data; and

~~providing an output to a user interface responsive to the data association of said at least two matched data pairs~~ calibrating the sensor data comprising said at least one matched data pair responsive to the association above a predetermined threshold.

60. (Currently amended) A computer system for evaluating the a quality of a calibration of an analyte sensor, the computer system comprising:

a sensor data module ~~that receives~~ configured to receive a data stream comprising a plurality of time spaced sensor data points from a substantially continuous analyte sensor;

a reference input module ~~that receives~~ configured to receive reference data from a reference analyte monitor, including ~~two~~ one or more reference data points;

a processor module ~~that forms two~~ configured to form one or more matched data pairs by matching reference data to substantially time corresponding sensor data, wherein the processor module is further configured to form and subsequently forms a calibration set including said no more than two or more matched data pairs for a single day;

~~a conversion function module that creates a conversion function using said calibration set;~~

~~a sensor data transformation module that prospectively converts additional sensor data into calibrated data using said conversion function; and~~

a quality evaluation module ~~that evaluates the~~ configured to evaluate a quality of said calibration set based on ~~a data an association of reference analyte data and substantially time corresponding sensor data for said at least one matched data pair selected from the group consisting of linear regression, non-linear regression, rank correlation, least mean square fit, mean absolute deviation, and mean absolute relative difference.~~

61. (Currently amended) A computer system for evaluating the a quality of a calibration of an analyte sensor, the computer system comprising:

a sensor data module ~~that receives~~ configured to receive analyte sensor data from a substantially continuous analyte sensor;

a reference input module ~~that receives~~ configured to receive reference data from a reference analyte monitor;

a processor module ~~that forms two or more~~ configured to form at least one matched data pairs pair by matching reference data to substantially time corresponding sensor data;

~~a conversion function module that creates a conversion function using said two or more matched data pairs;~~

~~a sensor data transformation module that converts sensor data into substantially real-time analyte values using said conversion function as sensor data is continuously or intermittently received from the sensor; and~~

~~a fail-safe module that controls the user interface based on the data association of said two or more matched data pairs~~ a quality evaluation module configured to evaluate a quality of said at least one matched data pair based on an association of reference data and substantially time corresponding sensor data for said at least one matched data pair, wherein the processor module is configured to calibrate the sensor data including said at least one matched data pair responsive to the association above a predetermined threshold.

62. (Currently amended) A method for evaluating the a quality of a calibration of a glucose sensor, the method comprising:

receiving sensor data from a glucose sensor, including one or more sensor data points;

receiving reference data from a reference glucose monitor, including one or more reference data points;

providing one or more matched data pairs by ~~matched~~ matching reference glucose data to substantially time corresponding sensor glucose data;

forming a calibration set including at least one matched data pair;

evaluating the a quality of said calibration set based on ~~data-association~~ a statistical analysis or a clinical acceptability analysis of at least one matched data pair; and

~~converting processing real-time~~ sensor data into-calibrated-data responsive to the quality of said calibration set above a predetermined threshold.

63. (New) The method of claim 58, wherein the step of evaluating a quality comprises evaluating the association using a statistical analysis.

64. (New) The method of claim 58, wherein the step of evaluating a quality comprises evaluating the association using a clinical acceptability analysis.

65. (New) The method of claim 58, further comprising calibrating the sensor data, wherein the step of calibrating is performed during initialization of the analyte sensor.

66. (New) The method of claim 58, further comprising calibrating the sensor data, wherein the step of calibrating is performed after initialization of the analyte sensor.

67. (New) The method of claim 58, further comprising calibrating the sensor data, wherein the step of calibrating is performed using a single matched data pair.

68. (New) The method of claim 58, further comprising calibrating the sensor data, wherein the step of calibrating is performed using more than one matched data pairs.

69. (New) The method of claim 58, wherein the step of receiving a data stream comprises receiving a data stream that has been algorithmically smoothed.

70. (New) The method of claim 58, wherein the step of receiving a data stream comprises algorithmically smoothing said data stream.

71. (New) The method of claim 58, wherein the step of receiving a data stream comprises receiving sensor data from a substantially continuous glucose sensor.

72. (New) The method of claim 58, further comprising calibrating the sensor data and displaying a graphical representation of the calibrated sensor data.

73. (New) The method of claim 59, wherein the step of evaluating a quality comprises evaluating the association using a statistical analysis.

74. (New) The method of claim 59, wherein the step of evaluating a quality comprises evaluating the association using a clinical acceptability analysis.

75. (New) The method of claim 59, further comprising calibrating the sensor data, wherein the step of calibrating is performed during initialization of the analyte sensor.

76. (New) The method of claim 59, further comprising calibrating the sensor data, wherein the step of calibrating is performed after initialization of the analyte sensor.

77. (New) The method of claim 59, further comprising calibrating the sensor data, wherein the step of calibrating is performed using a single matched data pair.

78. (New) The method of claim 59, further comprising calibrating the sensor data, wherein the step of calibrating is performed using more than one matched data pairs.

79. (New) The method of claim 59, wherein the step of receiving sensor data comprises receiving sensor data that has been algorithmically smoothed.

80. (New) The method of claim 59, wherein the step of receiving sensor data comprises algorithmically smoothing said sensor data.

81. (New) The method of claim 59, wherein the step of receiving sensor data comprises receiving sensor data from a substantially continuous glucose sensor.

82. (New) The method of claim 59, further comprising calibrating the sensor data and displaying a graphical representation of calibrated sensor data.

83. (New) The system of claim 60, wherein the processor module is configured to calibrate sensor data during initialization of the analyte sensor.

84. (New) The system of claim 60, wherein the processor module is configured to calibrate sensor data after initialization of the analyte sensor.

85. (New) The system of claim 60, wherein the processor module is configured to calibrate sensor data using a single matched data pair.

86. (New) The system of claim 60, wherein the processor module is configured to calibrate the sensor data using more than one matched data pairs.

87. (New) The system of claim 60, wherein said sensor data module receives a data stream that has been algorithmically smoothed.

88. (New) The system of claim 60, further comprising a data smoothing module that algorithmically smoothes a data stream received from said sensor data module.

89. (New) The system of claim 60, wherein said sensor data module is adapted to receive a data stream from a substantially continuous glucose sensor.

90. (New) The system of claim 60, wherein the processor module is configured to calibrate sensor data, and further comprising an output module configured to display calibrated sensor data.

91. (New) The system of claim 60, wherein the quality evaluation module is configured to evaluate the association using a statistical analysis.

92. (New) The method of claim 60, wherein the quality evaluation module is configured to evaluate the association using a clinical acceptability analysis.

93. (New) The system of claim 61, wherein the processor module is configured to calibrate sensor data during initialization of the analyte sensor.

94. (New) The system of claim 61, wherein the processor module is configured to calibrate sensor data after initialization of the analyte sensor.

95. (New) The system of claim 61, wherein the processor module is configured to calibrate sensor data using a single matched data pair.

96. (New) The system of claim 61, wherein the processor module is configured to calibrate sensor data using more than one matched data pairs.

97. (New) The system of claim 61, wherein said sensor data module receives sensor data that has been algorithmically smoothed.

98. (New) The system of claim 61, further comprising a data smoothing module that algorithmically smoothes sensor data received from said sensor data module.

99. (New) The system of claim 61, wherein said sensor data receiving module is adapted to receive sensor data from a substantially continuous glucose sensor.

100. (New) The system of claim 61, wherein the processor module is configured to calibrate sensor data, and further comprising an output module configured to display calibrated sensor data.

101. (New) The system of claim 61, wherein the quality evaluation module is configured to evaluate the association using a statistical analysis.

102. (New) The method of claim 61, wherein the quality evaluation module is configured to evaluate the association using a clinical acceptability analysis.

103. (New) The method of claim 62, further comprising calibrating sensor data, wherein the step of calibrating is performed during initialization of the glucose sensor.

104. (New) The method of claim 62, further comprising calibrating sensor data, wherein the step of calibrating is performed after initialization of the analyte sensor.

105. (New) The method of claim 62, further comprising calibrating the sensor data, wherein the step of calibrating is performed using a single matched data pair.

106. (New) The method of claim 62, further comprising calibrating sensor data, wherein the step of calibrating is performed using more than one matched data pairs.

107. (New) The method of claim 62, wherein the step of receiving sensor data comprises receiving sensor data that has been algorithmically smoothed.

108. (New) The method of claim 62, wherein the step of receiving sensor data comprises algorithmically smoothing said sensor data.

109. (New) The method of claim 62, wherein the step of receiving sensor data comprises receiving sensor data from a substantially continuous glucose sensor.

110. (New) The method of claim 62, further comprising calibrating sensor data and displaying a graphical representation of the calibrated sensor data.